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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,282	04/24/2000	RICHARD SETON TEDDER	6508.US.01	5742

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EXAMINER	
PENG, BO	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 12/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/402,282	TEDDER ET AL.	
	Examiner	Art Unit	
	Bo Peng	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-17,20,26,28-31,38, 40,42 and 59-95* is/are pending in the application.

4a) Of the above claim(s) *8,9,17-20,26,28-31,38,40,42 and 81-95* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,10-16 and 59-80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner of your application in the Patent and Trademark Office has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Bo Peng, Art Unit 1648.

Restriction election

2. The Office acknowledges the receipt of Applicant's restriction election, filed on July 16, 2004. Applicant elects Group I, claims 1-6, 8-16, and 59-80, without traverse.

3. Accordingly, claims 1-6, 8-16, 17, 20, 26, 28-31, 38, 40, 42 and 59-95 are pending. Claims 17-20, 26, 28-31, 38, 40, 42, 81-95 are withdrawn from consideration as being directed to a nonelected invention. Claims 8 and 9 are withdrawn from consideration as being dependent from cancelled claim 7. Claims 1-6, 10-16 and 59-80 are examined in the instant Office action.

Specification

4. Applicant is required to update the status of all parent priority applications in the first line of the specification. The status of all citations of US filed applications in the specification should also be updated where appropriate.

Claim objections

5. Claim 10 is objected to because of the following informality: Mutant HBsAg I should be "NP" HBsAg, not "NS" HBsAg. Appropriate correction is required.

Claim Rejections - 35 USC § 112, second paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 4, 6, 11, and 60-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. The term of "is capable of binding" in claims 1 and 11 is a relative term that renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the metes and bounds of the invention.

9. In claims 6 and 63-70, the phrase HBsAg mutant "an amino acid substitution within the sequence encoding amino acids 133 to 145 of HBsAg" is indefinite and confusing, because an amino acid sequence does not encode amino acids, or "an amino acid substitution" should not be within a nucleic acid "sequence encoding amino acids 133 to 145 of HBsAg", either.

10. Claims 4, and 60-62 recite that said amino acid substitutions are "in the region of the 'a' determinant". The claims are indefinite since the "region of the 'a' determinant" is not defined so that it cannot be determined what is excluded or included. One of ordinary skill in the art would not be reasonably appraised of the metes and bounds of the invention.

Claim Rejections - 35 USC § 112, first paragraph

11. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 13, 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

13. Since monoclonal antibodies are recited in the claims, it is essential to the invention recited in those claims. The hybridoma cells producing the monoclonal antibodies must therefore be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the hybridoma cells are not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the hybridoma cells. The specification does not disclose a repeatable process to obtain the hybridoma cells and it is not apparent if the hybridoma cells are readily available to the public. It is noted that applicants have deposited the hybridoma cells (p. 7), but there is no indication in the specification as to public availability.

14. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit will be made (see 37 C.F.R 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Applicant is directed to 37 CFR § 1.807(b), which states:
(b) A viability statement for each deposit of a biological material defined in paragraph (a) of this section not made under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure must be filed in the application and must contain:
(1) The name and address of the depository;
(2) The name and address of the depositor;
(3) The date of deposit;
(4) The identity of the deposit and the accession number given by the depository;
(5) The date of the viability test;
(6) The procedures used to obtain a sample if the test is not done by the depository; and
(7) A statement that the deposit is capable of reproduction.

Applicant is also directed to 37 CFR § 1.809(d) which states:
(d) For each deposit made pursuant to these regulations, the specification shall contain:
(1) The accession number for the deposit;
(2) The date of the deposit;
(3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and

(4) The name and address of the depository.

15. Claims 1-6, 10, 12, 16, 59-80 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

> *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detail chemical structure of the encompassed genus of undefined nucleotide fragment, proteins or polypeptides. Therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Lid.*, 18 USPQ2d 1016.
>
> Applicant has disclosed a limited number of species; therefore, the skilled artisan cannot envision all the contemplated amino acid sequence possibilities recited in the instant claims. Consequently, conception in either case cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. The sequences themselves are required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993).
>
> A description of a genus of protein sequences may be achieved by means of a recitation of a representative number of polypeptide sequences, defined by amino acid sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly&Co., 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

16. Claims 1-6, 10, 12, 16, 59-80 are directed to a genus, i.e. a monoclonal antibody that is capable of binding to wild-type HBsAg and to at least two mutant forms of HBsAg, wherein the at least one of said two mutant forms of HBsAg has a substitution in the "a" determinant or the region of the "a" determinant, wherein the HBsAg variants have an amino acid substitution within amino acids 133 to 145 of HBsAg, wherein the monoclonal antibody is an IgG, IgM or IgA, and further the monoclonal antibody is in a humanized form.

17. Since there is no specific structural features described on the mutant forms of HBsAg, nor "a" determinant, nor amino acids 133-145 of HBsAg, the mutant form of HBV is not defined and could be any peptide. Thus, the claims encompass a genus of monoclonal antibodies that are capable of binding to amino acids 133-145 of any known and unknown HBsAg. In order to provide evidence of possession of a claimed genus, the specification must provide sufficient distinguished identifying characteristics of the genus. In this case, Applicant has disclosed a few species, the antibodies that are able to bind two or three strains of NP and MAM HBsAg variants, which are IgG or IgA, but has not disclosed sufficient species for a genus of monoclonal antibodies that are capable of binding two of any known and unknown HBV as broadly claimed. Consequently, while the skilled artisan would reasonably conclude Applicant was in possession of a few monoclonal antibodies to HBsAg, which are IgG and IgA, there is no indication that Applicant was in possession of a monoclonal antibody of IgM to HBsAg, nor a monoclonal antibody in a humanized form, nor all monoclonal antibodies to has an amino acid substitution within amino acids 133 to 145 of HBsAg, nor a genus of monoclonal antibodies that is capable of binding specifically to wild-type HBsAg and to any two known or unknown HBsAg variants as broadly claimed.

Claim Rejections - 35 USC § 102

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

19. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Waters (WO 94/21812).

20. Claim 11 is directed to a monoclonal antibody that is capable of binding to at least one HBV mutant that has point mutations at any one or more of amino acid(s) 143, 144 and 145 in its "a" determinant of HBsAg.

21. Waters teaches a monoclonal antibody, SMH HBs 145, that can bind to a HBV variant, which contains a glycine to arginine substitution mutation at position 145, which is within the "a" determinant region. Thus, the instant invention is anticipated by Waters.

Remarks

22. No claims are allowed.

22. Claims 13-15 are free of the prior art. The Examiner is not aware of any suggestion in the prior art that would point the artisan to the claimed monoclonal antibodies P2D3, M3A10 and M4F5, which specifically bind to two strains of HBV variants having amino acids Ile 133, His 134 and Val 144, as well as Ile 133, Asn 134, Ser 142, leu143 and lys145 in the amino acid sequence of HBsAg.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

JEFFREY STUCKER
PRIMARY EXAMINER

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